



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,094	05/20/2002	Harry Holthofer	112958.120US1	5729

24395 7590 08/02/2005

WILMER CUTLER PICKERING HALE AND DORR LLP
THE WILLARD OFFICE BUILDING
1455 PENNSYLVANIA AVE, NW
WASHINGTON, DC 20004

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,094

Applicant(s)

HOLTHOFER, HARRY

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2001 and 14 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-27 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 4-6, 11-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:
 - I. Claims 1, 2, 24-27, drawn to an isolated nucleic acid encoding a soluble nephrin or soluble nephrin-like molecule.
 - II. Claims 4 and 5, drawn to soluble nephrin-like molecules.
 - III. Claim 6, drawn to a binding substance capable of binding to a soluble nephrin-like molecule.
 - IV. Claims 11 and 17, drawn to a method of diagnosing a subject suffering from diabetes and other nephropathies employing soluble nephrin-like molecules.
 - V. Claims 12 and 18, drawn to a method of evaluating the efficacy of treatment in a subject suffering from diabetes and other nephropathies employing soluble nephrin-like molecules.
 - VI. Claims 13 and 19, drawn to a method of screening for the susceptibility of a population to nephropathies employing soluble nephrin-like molecules.
 - VII. Claims 14 and 20, drawn to a method of diagnosing a subject suffering from diabetes and other nephropathies employing a binding substance capable of binding to a soluble nephrin-like molecule.
 - VIII. Claims 15 and 21, drawn to a method of evaluating the efficacy of treatment in a subject suffering from diabetes and other nephropathies employing a binding substance capable of binding to a soluble nephrin-like molecule.
 - IX. Claims 16 and 22, drawn to a method of screening for the susceptibility of a population to nephropathies employing a binding substance capable of binding to a soluble nephrin-like molecule.

Art Unit: 1644

X. Claim 23, drawn to a method of treating a patient with a nephropathy employing an isolated nucleic acid encoding a soluble nephrin or soluble nephrin-like molecule.

3. The inventions listed do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Kestila et al. (1998, IDS) teaches the nucleic acid and nephrin-like molecule of Groups I and II, respectively.

Since Applicants' inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

4. Accordingly, Groups I-X are not so linked as to form a single general inventive concept and restriction is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/018,094

Page 4

Art Unit: 1644

A handwritten signature in black ink, appearing to read 'G.R. Ewoldt', with a date '1/29/05' written below it.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600